EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-01

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-16-011	11/01/2016 To 06/30/2018 Base Option Period Number 1	Activities to Support Understa

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1,3.3,3.6,3.8

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 07/01/2017 To 06/30/2018

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2016 To 06/30/2018		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1101 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Noelle Mills (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2171 FAX Number:

Performance Work Statement (PWS)
ICF Contract # EP-C-16-011
Work Assignment #1-01

Title: Activities to Support Understanding Health Risks from Exposure to Pathogens in Water

Work Assignment Contracting Officer's Representative (WACOR):
John Ravenscroft (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Alternate WACOR: Sharon Nappier (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Telephone #: 202-566-0740
E-mail: nappier.sharon@epa.gov

Contract PWS: 3.1, 3.3, 3.6, 3.8

Period of Performance: July 1, 2017 through June 30, 2018

**Note: No confidential business information (CBI) data will be needed in the course of this work assignment.

Goals and Objectives:

The overall objective of the tasks in this work assignment is to inform the Agency on the human health risks associated with exposure to pathogens in water. Specific goals are:

a. Provide decision-makers an improved understanding of pathogen-associated risks in ambient and drinking waters, utilize results from existing health studies (e.g., epidemiological, quantitative microbial risk assessment (QMRA), illness outbreak reports, etc.), provide risk information on waters where epidemiology data or other health studies are currently lacking.
b. Refine the Agency's understanding of the risk differences that exist for different fecal contamination sources and how those risks relate to the observed health risks reported by epidemiological studies conducted in fecal pollution-impacted waters.
c. Further refine the Agency's understanding of the human health risks from exposure to waters affected by wet weather-associated loadings of pathogens.
d. Aid the Agency in understanding how different exposure profiles (e.g., life stage-specific, drinking water, and recreational water) can affect human health risks.

e. Inform the Agency on inclusion of multiple water quality measures in a matrix (e.g., a 'toolbox') to help identify hazardous conditions and inform decision-making.

Background: The Environmental Protection Agency (EPA) is interested in understanding the links between the source(s) of pathogens (e.g., the nature and magnitude of fecal loadings to surface waters), how the sources of pathogens affect the pathogen profile reaching waterbodies, the relationships between pathogen profiles and the surrogates used to gauge waters quality, and the parameters considered to estimate exposure. While the studies used to inform previous criteria recommendations have been conducted in waters impacted by human sources of contamination under dry weather or base flow conditions, EPA would like to better understand the risks associated with other fecal sources and wet weather impacts to surface waters. Quantitative Microbial Risk Assessment (QMRA) has been identified as a tool that the Agency can use to complement existing epidemiological and other health data and better understand the relative risks associated with other sources of surface water contamination. The Agency's previously supported QMRA efforts have indicated that there are potentially significant differences in health risks associated with different sources of fecal contamination. This work assignment covers various aspects of further development and application of QMRA in support of criteria development and implementation. This work assignment also includes the consideration of other types of health study information, such as epidemiological results, to provide an increased understanding of the potential health effects from exposure to pathogens in water.

Quality Assurance: The tasks (Tasks 2 and 4) in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the approved ICF March 2017 Programmatic QAPP (pQAPP) to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers secondary data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the QA/QC procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

Performance Work Statement (PWS): The scope of work in this PWS will fall under the following task areas:

Task 1: *Work plan, monthly progress reports and quality assurance*

Task 1.1. Work plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task 1.2. Monthly Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task Area 1.3. Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information) and shall complete the complete OW IQG Checklist as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this work assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

Task Area 2: *General Project Support*

EPA is interested in furthering the development of the QMRA process for criteria implementation and as a process for water quality management for various waterbodies. There are numerous varied tasks within this QMRA-related work assignment. The various tasks in this work assignment necessitate a comprehensive overview and planning process for the work assignment goals to be realized. The scope of this task falls into two main areas: project management support and project communication support.

Task 2.1: Project planning and management

The contractor shall conduct project strategic planning in conjunction with the WACOR. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency timeline for completing tasks within this work assignment, such as publishing Recreational water criteria and implementation guidance. For each task area, the contractor shall work with the WACOR to develop a project plan, including scope, goals, and timelines.

This task will require contractor travel to EPA for an initial planning meeting and quarterly update meetings (at a minimum) thereafter during the period of performance of this work assignment. The contractor shall provide personnel knowledgeable in technical areas (e.g., QMRA, microbial ecology, public health, and epidemiology) and project planning and management for this process. Expertise in Microsoft Project is preferred. The initial meeting for each task area is crucial to the entire overall work assignment and therefore will need to occur as one of the first steps after work has begun on this work assignment.

Deliverables under this subtask will include a Gantt chart timeline listing all related tasks with interim and final deliverable dates and quarterly project updates delineated. As part of the deliverables under this subtask, the contractor shall include a discussion on the Agency's project goals and objectives and how each of the tasks supports them. It is hoped that this exercise will also help to identify any gaps that will need to be addressed prior to the publication of deliverables.

Task 2.2: Project communication support:

EPA needs to communicate its efforts to a broad audience. From engaging other scientists on technical issues to discussing regulatory actions with stakeholders and the public, EPA needs to be keenly aware of effective communication strategies. For all tasks under this work assignment, the contractor shall discuss with the WACOR ways to achieve effective communication objectives. The audience for specific deliverables may be different even though the analytical approach may be similar. Questions to cover with the WACOR should address the audience and purpose of the deliverable, ideas for finding effective presentation strategies, suggestions for achieving the communication objectives given differing formats (e.g., written versus oral). The contractor shall, based on technical direction given by the WACOR, provide support in preparing interim project updates and other materials for internal and external audiences. These may include but are not limited to short briefing documents and PowerPoint presentations. The contractor may also be requested to participate in and/or conduct briefings and meetings. The contractor may also be requested to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The contractor shall coordinate with the WACOR for the proper timing and need for these activities. A weekly update call with the WACOR will be required for this task, as needed.

Work under meeting-related activities and travel-related expenses shall not occur until approval is obtained and provided by the CL-COR.

Task 2.3: Development of Technical Support Documents

EPA has been developing technical support documents to help state and local agencies implement criteria recommendations. These documents also aid others in EPA to evaluate standard package submissions that may contain technical differences compared to EPA recommendations.

EPA developed two documents that have been internally and externally peer reviewed and have gone through two steps of management review. The contractor shall support the EPA WACOR with comment response, document revision and finalization of the document for publication by EPA. The two documents are: 1) Site-Specific Alternative Recreational Criteria Technical Support Materials for Alternative Health Relationships, and 2) Site-Specific Alternative Recreational Criteria Technical Support Materials for Predominantly Non-Human Fecal Sources. These documents will need to be revised in response to final management comments and finalized for publication clearance. Communication materials (e.g., fact sheets, management briefings, etc.) will need to be prepared to support the finalization. The contractor shall discuss with the WACOR the specific communication strategy for each document to determine what specific materials will be needed.

Task 3: *Characterization of Human Health Risks from Exposure to Pathogens in Water*

This task area is to support EPA with collating, developing and interpreting health study information that characterizes the human health effects from exposure to pathogens in water. Because microbial and chemical surrogates are used to routinely gauge water quality and estimate the potential for risk, this task will also need to consider how the surrogates relate to the pathogen profile and the effectiveness of various surrogates for predicting the hazardous condition. This task includes the evaluation and interpretation of different types of health study information (e.g., epidemiological, QMRA, clinical, outbreak information, etc.) to provide context for criteria development (or other regulatory-related) activities and for decision-makers. Specific tasks are listed below, but additional tasks may be needed due to the iterative nature of risk assessment and the risk management questions being addressed.

Task 3.1: Systematic Literature Searches

The contractor shall support EPA with the conduct of systematic literature searches and retrieval of information from the scientific literature on topic relevant to the task areas in this work assignment. HECD has been developing a SOP for systematic literature review that the contractor shall utilize for this purpose. Before any searching and collation of information is conducted, the contractor shall discuss with the WACOR the purpose and scope of the search, including search terms; the strategy for screening the search results, including a rationale for identifying information used and not used; and, for substantiating data quality for items used in deliverables.

Task 3.2: Marion et al. study

Another epidemiology study was published in 2010 that examined a small inland lake in Ohio affected by point and non-point human sources (Marion et al, 2010). This small scale study also used fecal indicator bacteria cultural methods to estimate water quality. EPA is already using this water quality data in efforts for comparing various enumeration methods. The availability of this data would also serve useful to demonstrate the applicability of the previous developed QMRA models to a human impacted freshwater inland lake. In addition to evaluating the epi data as with the other anchoring efforts, the contractor shall replicate EPA's previous efforts with reverse QMRA anchoring efforts in coastal freshwaters using the data from this small scale epi study. The contractor shall also evaluate the application of the QMRA process at such a small waterbody (i.e., given the potential longer term goals of applying QMRA in estimating risk in a specific type of waterbody affected by a specific source, the contractor shall use this exercise to evaluate the application of the QMRA process in this context). The contractor shall evaluate watershed information for fecal sources potentially affecting the study location. The goal of this task is to produce a risk-based evaluation of the water quality extant at the study location. The deliverable for this task will be a report suitable for publication in a peer-reviewed science journal.

Task 3.3: Boquerón

EPA conducted two parallel efforts in Boquerón, Puerto Rico during the summer of 2009. One effort was a full scale epidemiology study and the second was a significant water quality monitoring effort that included the enumeration of pathogens and fecal indicator organisms at the beach and at the potential sources affecting the beach. EPA has conducted additional analyses to better understand potential risks from the various fecal sources affecting the beach. The contractor shall utilize the data from these efforts to further refine the analysis to improve the understanding of recreator risks and to help with identifying the hazardous condition. The contractor shall coordinate with the Office of Research and Development in using the epidemiology data.

Additional questions to address in this QMRA include:

What do the epi and monitoring data, as well as the risk assessment results, suggest about the potential fecal sources affecting the Boqueron beach?

Given the level of pathogens detected during the monitoring, what levels would have been needed (e.g., enteric viruses) in order for this beach to show a similar health relationship to fecal indicators as studies conducted at other marine beaches?

Do the results suggest that population immunity was a confounding factor in the epi study (i.e., can the risk assessment health modeling examine such potential background immunity in a sensitivity analysis)?

Task 3.4: QMRA to improve the understanding of risks related to exposure

Communication of swimming-associated risks in recreational waters affected by fecal contamination can be confusing. Risk estimates are based on health studies conducted at a small number of beach sites, representative of a very narrow fecal contamination scenario, and are then generalized to the broader set of waters with the recreation designated use. Numerous studies have demonstrated that the level of water quality recommended by EPA's recreational water quality criteria can correspond to markedly different risk profiles. Of particular concern, human sources of fecal contamination can pose the highest relative risk levels; however, risk managers have been slow to incorporate this information and instead rely on a 'one size fits all' approach that assumes all recreational waters are just like those that are characterized during empirically-based health studies conducted at a few discrete locations. This approach can translate into significant under-protection of human health in some types of waters and can lead to possible misinterpretations of what risks really mean and 'safe to swim' decisions.

This task includes the development of exposure profiles for specific exposure routes of pathogens in water (e.g., drinking, recreational). The profiles may be for specific life stages or be representative of the populations included in empirical studies. The contractor shall utilize EPA's *Exposure Factors Handbook* and other information to inform the development of the profiles.

QMRA can be used to evaluate the risks associated with the exposure profiles and include a characterization of risks from different activities, different pathogen profiles, and different life stages. This task will integrate those various parameters and factors into a methodical framework to assess risk and inform decision-making.

Task 3.5: Understanding risks associated with wet weather impacts on water quality

Most of the health information available was developed under dry weather or base flow conditions. Very few health studies have characterized wet-weather-associated health effects specifically as part of the study design. The surrogates used to evaluate water quality increase substantially following wet weather, but there doesn't appear to be a concomitant increase in pathogen-related risks. Health study information suggests that wet weather-associated pathogen risks can be lower at substantially higher levels of indicator. The purpose of this task is to design an analysis to help inform the discussion at EPA on how to consider the impacts of wet weather on pathogen-related risks.

This task will involve: searching the literature (see Task 3.1), constructing hazard profiles for both dry and wet weather events, evaluating exposure related to wet weather, consideration of water quality metrics that may differ from those traditionally used, and estimating human health risks, including a relative understanding of risks under different conditions. The contractor shall conduct project planning with the WACOR.

Task 3.6: Understanding water quality metrics, how they relate to risk, and the 'toolbox'

The traditional approach with measuring water quality and assessing the potential for pathogen-related risks is to utilize a very limited number of culture-enumerated fecal indicator bacteria.

These bacteria may function as good surrogates under certain conditions, but are inadequate under other conditions. The science related to alternative water quality metrics, including other indicator organisms, source-specific surrogates, direct detection of pathogens and the application of other enumeration methodologies, has progressed substantially over the last 35 years. To date, this information has not been included into the regulatory framework despite numerous examples around the country where this additional information has been used to inform decision-making and improve public health protection.

The purpose of this task is to systematically evaluate the state of the science related to water quality metrics used to measure water quality for estimating the potential risks from pathogens. The goal of this task is to develop a 'toolbox' of metrics that can be used by EPA, states, and others that consists of multiple water quality metrics that can be utilized based on a number of factors to provide improved assessments and better inform decisions.

This tasks may involve literature searches and the development of reports that cover the various metrics available, conditions that may support or preclude their use, methodological approaches, and interpretation of results in context with EPA recommendations. The contractor shall conduct project planning with the WACOR.

Based on available information, QMRA may be used to estimate levels of various water quality metrics at discrete levels of protection.

Task 3.7: Understanding and interpreting health study results from different types of studies and experimental designs.

EPA considers a range of different types of health studies as it collates, evaluates and discusses the state of the science used to inform decision-making. The various health studies examined are often conducted under a range of conditions, potentially represent different relationships between health and water quality metrics, and the results suggest that their interpretation and application should be considered in context with other studies. EPA is interested in examining how to compare health study results; potentially using a level of health protection as a pivot point to connect study results generated by different methodological approaches. Using QMRA analyses to compare the exposure profiles characterized in different study types could also provide needed context for the Agency.

The contractor shall conduct the following activities:

a) Evaluate a cut-point analysis approach using indicator data associated with health effects (e.g., enterococcus qPCR and NGI) to characterize potential levels of water quality indicative of significant increases in health risks.
b) Evaluate available health study information for the potential health burden experienced by children. Use QMRA to characterize empirical epidemiological results.
c) Coordinate with the investigators on an RCT (randomized control trial) study to obtain the raw data from that study and re-analyze the results using the statistical methods employed by Wade and colleagues for the NEEAR (national

epidemiologic and environmental assessment of recreational water) studies. This analysis will provide an indication of whether or not results from RCTs and PCs can be compared directly and will help to answer the question of whether the differences observed in existing epidemiology studies are due to the study design or other factors.

d) Use a QMRA framework to translate results from an RCT to one that is comparable to a PC study. Conduct sensitivity analyses to identify the model parameters that most strongly influence the results. Compare the results with those from (a) above if RCT data is available.
e) If the sensitivity analyses indicate that the volume of water ingested is a critical component, conduct a screening-level analysis using the exposure protocol specified by the RCT epidemiology studies. This study will determine if the volume of water ingested during the RCT epidemiology studies are likely to differ substantially from those that are generally used to characterize exposure volumes.
f) Extend the work reported by Boehm (2007) using culturable and molecular methods for the indicators of highest interest in several disparate recreational waterbody types of interest. This information would help to characterize the extent to which the method of allocating exposure to the subjects influences the results. If the density of indicators is highly variable in short spatial and temporal frames, differences in exposure sampling prescribed for RCT versus PC based epidemiological studies will not have a large influence on study results.
g) Report findings to EPA in a memorandum, including potential next steps for this analysis.

General Requirements of the Work Assignment and Schedule:

Due Dates: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.
Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.
Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.
Final Documents: The contractor shall submit final documents both electronically and in hardcopy to the WACOR.

Milestones and deliverables

Milestone	Task	Due Date
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Per contract requirements

Development of contract level QAPP for Secondary Data	1.3	Within 20 calendar days of receipt of work assignment
Revised contract level QAPP for Secondary Data based on EPA comments	1.3	Within 20 calendar days of receipt of EPA comments
Task 2: General Project Support		
Project Planning and Management	2.1	Initial planning meeting to be held within 20 calendar days of receipt of work assignment. Final project Gantt chart, goals and objectives statement, and gap analysis due within 2 weeks of initial meeting. Drafts of these deliverable would be expected at the close of the initial meeting. Subsequent meetings to be held roughly every quarter thereafter.
Project Communications Support	2.2	After workplan approval, throughout the period of performance. Other communication materials will be dependent on the analytical results.
Development of Technical Support Documents	2.3	After workplan approval, the contractor shall meet with the WACOR within 20 calendar days to discuss comment response and revisions. A timeline shall be developed for each document at that meeting.
Task 3: Characterization of Human Health Risks from Exposure to Pathogens in Water		
Systematic Literature Searches	3.1	After workplan approval, throughout the period of performance for topics in received via technical direction.
Marion anchoring QMRA	3.2	After workplan approval, draft report for management review within 4 weeks.
Boqueron QMRA	3.3	After workplan approval, project planning meeting within 20 calendar days to discuss methodological approaches.
QMRA to improve the understanding of risks related to exposure	3.4	After workplan approval, project planning meeting within 20 calendar days to discuss scoping and analytical approach.

	Understanding risks associated with wet weather impacts on water quality	3.5	After workplan approval, project planning meeting within 20 calendar days to discuss scoping and analytical approach.
	Understanding water quality metrics, how they relate to risk, and the 'toolbox'	3.6	After workplan approval, project planning meeting within 20 calendar days to discuss scoping and analytical approach.
	Understanding and interpreting health study results from different types of studies and experimental designs.	3.7	After workplan approval, project planning meeting within 20 calendar days to discuss scoping and analytical approach.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-02

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-16-011	11/01/2016 To 06/30/2018 Base Option Period Number 1	Children's risks from microbia

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1, 3.3, 3.6, 3.8

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 07/01/2017 To 06/30/2018

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2016 To 06/30/2018		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:		Cost/Fee	LOE:
Cumulative Approved:		Cost/Fee	LOE:

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1101
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Contracting Official Name: Noelle Mills (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2171
	FAX Number:	

Performance Work Statement
ICF Contract EP-C-16-011
Work Assignment # 1-02

Title: Children's risks from microbial contamination in recreational water

Period of Performance: July 1, 2017 through June 30, 2018

Work Assignment Contracting Officer Representative (WACOR):

John Ravenscroft (Mail Code 4304T)
U.S. Environmental Protection Agency (US EPA)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Alternate WACOR:

Shamima Akhter (Mail Code 4304T)
U.S. Environmental Protection Agency (US EPA)
Health and Ecological Criteria Division
Office of Science and Technology, Office of Water
1200 Pennsylvania Avenue, NW
Washington DC, 20460
Phone: 202-566-1341
E-mail: akhter.shamima@epa.gov

****Note: No CBI data will be needed in the course of this work assignment.**

Contract SOW: 3.1, 3.3, 3.6, 3.8

Goal: The overall goal of this performance work statement (PWS) is to examine multiple lines of evidence, such as the Centers for Disease Control (CDC) Recreational Water Illness outbreak data, exposure studies, risk assessment analyses and epidemiological data, to evaluate the potential that children have disproportionate risks of waterborne illness from recreational water contact.

Objectives:

1. Produce a comprehensive report for internal EPA evaluation detailing the known health information for children's waterborne illnesses from recreational water exposure. The report shall demonstrate an evaluation of the scientific literature, risk analysis (e.g., QMRA) and observational results (e.g., National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) study reports).

2. Produce a draft and final report for external scientific peer review based on the information covered in objective 1.

3. Produce communications materials to accompany reports including: a 1 to 2 page nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the WACOR via technical direction.

Background: A growing body of scientific knowledge has demonstrated that children may suffer disproportionately from environmental health risks and safety risks. These risks occur because 1) children's neurological, immunological, digestive, and other bodily systems are still developing; 2) children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; 4) children's size and weight may diminish their protection from standard safety features; and 5) children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves.

The importance of identifying and assessing risks to children was made in Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risk[1], which states:

> "to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:
>
> (a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.
>
> 1-102. Each independent regulatory agency is encouraged to participate in the implementation of this order and comply with its provisions."

The U.S. Environmental Protection Agency (EPA)'s Policy on Evaluating Risks to Children[2] :

> "considers the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision making process, including the setting of standards to protect public health and the environment. To the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done -

[1] Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks. http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm

[2] Policy on Evaluating Health Risks to Children. http://www.epa.gov/osa/spc/pdfs/memohlth.pdf

for example, a demonstration that infants and children are not expected to be exposed to the stressor under examination."

The US EPA's Office of Children's Health Protection[3] conducts research and supports risk assessments to assess children's risks and susceptibility to environmental contaminants (chemicals, toxins, air pollutants). However, it not clear the extent, to which, children suffer disproportionate exposures and health outcomes as a result of exposure to pathogens, or other microbial-related risks, found in recreational surface waters. Few epidemiological data and quantitative risk assessments have explored children's risks from microbial contaminants found in water, limiting the ability to determine if children experience different responses to waterborne fecal indicators and pathogens, or develop illness rates as a result of recreational water contact in the United States. Risks in children have specifically not been explored separately, but they are included as part of the general populations in most epidemiological studies.

Under the auspices of the Clean Water Act (CWA), the Agency regulates recreational water, and sets numeric indicator bacteria criteria (*Escherichia coli*, Enterococci) in surface (ambient) waters used for the purpose of recreational water contact. EPA issued new CWA 304(a) recreational ambient water quality criteria in December 2012. The science underpinned the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA would like to better understand the risks posed to children associated with recreational exposures. This work assignment covers efforts to develop and disseminate the current understanding in this area.

Task Knowledge and Skills Required: The contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed. The contractor shall also be proficient in R programming and other relevant statistical tools. The contractor shall have practical experience in environmental microbiology, epidemiology, and statistical methods and analysis and have advanced credentials in statistics or environmental engineering. The contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development. The contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

Quality Assurance: The tasks (Tasks 2 -4) in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the approved ICF March 2017 Programmatic QAPP (pQAPP) to assure the quality of the data used under this work assignment. The scope of the March

[3] The Office of Children's Health Protection.
http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm

2017 pQAPP covers secondary data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the WACOR before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the QA/QC procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

Performance Work Statement (PWS): The contractor shall provide technical support in the evaluation of children's risks from exposure to microbial contamination in recreational waters. The scope of this PWS will fall under the following tasks:

Task 1: ***Work Plan and monthly progress reports (MPR)***

Task Area 1.1. Work Plan
The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task Area 1.2. Monthly Progress Reports
This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoiced LOE and costs delineated by the tasks in this WA. The contractor shall provide the WACOR with regular updates detailing progress.

As described in the Quality Assurance Section, the contractor must follow the ICF submitted March 2017 pQAPP for the use of existing data and, if applicable, application of peer reviewed existing model. The monthly progress report shall indicate, in a separate QA section, whether significant project-specific QA issues have been identified and how they are being resolved.

Task Area 1.3. Information Quality Guidelines
The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (http://www.epa.gov/quality/informationguidelines/) and shall complete the Checklist for Influential Information, as needed, for each deliverable from this work assignment. The WACOR will provide this checklist to the contractor. The contractor shall have a teleconference with the WACOR before the initiation of Task 2 to discuss the Information Quality Guidelines and the contractor's role in completing the checklist. At the end of the work assignment, the contractor shall provide a memorandum describing how the planned product(s) developed for this work assignment meet with EPA's Checklist for Influential Information and documenting the quality assurance procedures that were used in developing the deliverables under this PWS.

Task Area 2: *Characterize children's health risks from microbial contaminants.*

Understanding children's risks and their life stage-specific exposure patterns has been an ongoing effort at EPA. The WACOR will provide the contractor with the background information that has already been collected in this area. The contractor shall use this information as a starting point to develop the project report. The contractor shall conduct literature searches for the years 2011 to the present in the area of children's exposure parameters and health effects children experience following exposure to microbial contamination in surface waters. References collected, but not used will also require proactive justification. The contractor shall leverage efforts under other work assignments, such as 1-03 (The development of cyanotoxin ambient water quality criteria), with this task as the criteria contains an assessment of children's exposure parameters. The contractor shall ensure that no duplication of effort occurs, such as searching the scientific literature or evaluating sensitive subpopulations.

For this task, the contractor shall characterize the biological, immunological (resistance, immunity), social and behavioral factors impacting children's risks from microbial contaminants in water. These contaminants can include infectious and pathogenic microorganisms, as well as, microbial constituent compounds (e.g., phytocyanins) or produced by microbes (e.g., cyanotoxins).

The contractor shall compile available data on waterborne organisms associated with recreational water illness (viruses, fungi, protozoa, bacteria) using published data. This effort includes extending or building upon compilations already conducted in HECD. The contractor shall create appropriate and effective graphics to identify organisms most frequently associated with adverse health effects in children vs. adults. Where possible, the contractor will report frequency and occurrence data by regions or other delineation as specified by the WACOR. This task will provide a high level summary of the burden of illness posed by waterborne pathogens.

The contractor shall evaluate the peer-reviewed and published literature including government publications and reports (e.g., EPA, CDC, USDA, FDA, and WHO) to characterize factors that impact children's response to infections or other health

endpoints. The contractor shall address the following key points:

1) What are the biological processes/characteristics that differentiate children from adults related to waterborne infections and illnesses?
2) What immunological processes impact children's responses to waterborne infectious or other microorganisms?
    a. Explore the issues of resistance
    b. Self-limiting disease
    c. Immunity and age
3) Identify and review behavioral studies in the literature to identify behaviors in children that impact recreational water exposure to fecal contamination
    a. Ingestion studies
    b. Hand to mouth studies, and
    c. Hand washing behavior

The contractor shall assess epidemiologic studies (EPA NEEAR cohort studies, other studies in the United States, cohort studies, as well as RCT/ randomized studies from international sites) to document human health endpoints from recreational water contact. The discussion should discuss key health endpoints in the study populations related to illness rates in children versus adults.

Specifically, for waterborne infectious pathogens, the contractor shall address the following key points:

1) Which microorganisms are known to cause the most frequent illnesses in children?
2) Are there specific sources of infection, transmission routes or infectious doses in recreational waters that have a differential effect on children?
3) Are there specific age groups of children that are susceptible to different pathogens?
4) Describe any evidence of illness severity or differences in severity between lifestages for specific pathogens or other microbial exposures. Evidence of severity such as hospitalization, transplants, and sequelae from recreational water.
5) Identify infection source, transmission routes, and infectious doses from recreational water.

The contractor shall compile available Centers for Disease Control and Prevention outbreak data on waterborne organisms associated with recreational water illness in ambient/surface waters and pools in the United States using published data. Other outbreak information available from the peer reviewed scientific literature shall be considered here too. The contractor shall create appropriate and effective graphics to identify organisms most frequently associated with children vs. adults, including organism type and water body/source.

The contractor shall address the following key points:

1) Identify the populations, venues/waterbody types (lakes, streams, ocean, rivers etc)
2) Provide descriptions on how children are categorized (age, ethnicity, gender)
3) Identify which subsets of children are most impacted by RWI, where possible
4) Identify risk factors for illness
5) Identify the most prevalent waterborne pathogens in RWI for children
6) Incorporate results of environmental monitoring (e.g. which pathogens were assessed in the water body/sample, method of detection, species detected, prevalence)
7) How are illness rates and severity different between the exposed children and adults?
8) Create a ranking of the most prevalent RWI and health outcomes across all age groups, where the data permits

The contractor shall summarize and compare illness rates/health outcomes from the outbreak, epidemiologic or other health studies for children versus adults. Published risk assessments (e.g., quantitative microbial risk assessments (QMRA)) shall also be considered. More recent epidemiological analyses have suggested that there is a risk differential for children. Part of this analysis shall evaluate the context for the reported risk differential (e.g., sources of pathogens, exposure differences, study locations, fecal loading profiles, etc.). Outcomes may be expressed as relative risks, odds ratios, fatality rates/deaths, and should include confidence levels. Tables, figures or other appropriate graphical representation should be employed.

EPA is interested in evaluating these various areas in the development and implementation of new recreational ambient water quality criteria (AWQC). The contractor, in conjunction with the WACOR, shall develop risk-based analyses based on EPA's previous QMRA efforts and incorporating updated exposure profiles using the information gleaned from the above efforts. For example, the NEEAR epi studies did not report a significant health relationship with fecal indicator bacteria (FIB) for children (as opposed to the general population in the study). Given that children tend to have higher exposures while recreating, ingest more water when recreating (see Dufour study results – will be provided by the WACOR), may be more susceptible to infection (e.g., norovirus), and can have more severe outcomes once infected (e.g., E. coli O157) could the exposure profile (i.e., their behavior in shallow water) for children have an ameliorating impact? NEEAR also did not report significant health relationships in shallow water; precisely where most children are exposed. The contractor shall utilize existing QMRA approaches and epidemiology and/or other health information to evaluate the potential impacts of the exposure profile of children on the expected results for human health risks.

Understanding children's risks and their life stage-specific exposure patterns has been an ongoing effort at EPA. The WACOR will provide the contractor with the background information that has already been collected in this area. The contractor shall use this information as a starting point to develop the project report. The contractor shall conduct literature searches for the years 2011 to the present in the area of children's exposure parameters and health effects children experience following exposure to microbially-contaminated surface waters. References collected, but not used will also require proactive justification. The contractor shall leverage efforts under B-03 (The development of cyanotoxin ambient water quality criteria) with this task as the criteria contains an assessment of children's exposure parameters. The contractor shall ensure that no duplication of effort occurs, such as searching the scientific literature or evaluating sensitive subpopulations. The contractor shall prepare and submit a draft report for EPA technical review detailing the information collected and analyzed for the evaluation of human health risks to children from recreational exposure to ambient waters affected by microbial contamination. Phone calls and on-site meetings may be required to discuss the weight of evidence provided by the contractor.

The contractor shall revise the report based on the comments submitted by the WACOR and discuss options for addressing the comments with EPA. The contractor shall also prepare effective communication materials to accompany the draft report for use in internal and eventually external communication efforts (see Task 3).

The report may undergo multiple edits and the contractor is expected to respond to EPA comments. This document will need to be formatted as directed by the WACOR. The contractor shall incorporate comments on any draft deliverables from the WACOR. Also, the contractor shall update information in the report as needed to capture any developments related to ongoing studies. The report shall be compliant with Section 508 of the Rehabilitation Act when finalized and submitted (see http://www.epa.gov/accessibility/index.htm).

The contractor shall prepare and submit a version of the final report based on the deliverable that would be suitable for external scientific peer review. The contractor shall submit a draft to the WACOR for Agency clearance. When all Agency comments have been addressed, that version may be submitted for peer review. The venue for the peer review is currently undetermined. The contractor shall address peer reviewer comments in conjunction with the WACOR. This document will need to be formatted for publication as directed by the WACOR.

> *Travel:* No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 3: *Communication materials*

As specified in the Task 2, the contractor shall prepare, in conjunction with the WACOR, materials to assist in communicating the complex technical aspects of the project results to both non-technical and technical (but not academic) audiences (both internal and

external to the Agency). These materials will most likely consist of synopses, executive summaries, Q&As, presentation slides, etc. and each may be aimed at a particular audience or to tailored for the communication need. The contractor shall coordinate with the WACOR on the scope and nature of these materials for specific audiences.

Task Area 4: *General Project Support*

The contractor shall, based on technical direction given by the WACOR, provide support in preparing interim project update sand/or other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor may be requested to participate in and/or conduct briefings and/or present at meetings.

Task No.	Milestones/Deliverable*	Schedule
1	1.1 Workplan	Per contract requirements
1	1.3 Information Quality Guidelines	Submitted with final deliverables
2	Perform literature search to gather the most recent information of children's exposure patterns, susceptibility and risks from microbial contaminants in water.	Within 1 month of workplan approval.
2	Evaluate existing health information for children's exposure to microbial contaminants in water. Discuss results with WACOR	Within 2 months of workplan approval
2	Submit draft report for EPA review	Within 2 weeks of discussion of results with WACOR
2	Respond to EPA reviewer comments	Within 2 weeks of receiving EPA comments
2	Submit final report to EPA for peer review clearance	Within 2 weeks of addressing comments
2	Respond to peer reviewer comments	Within 2 weeks of receiving comments
3	Prepare risk communication presentation materials for technical and non-technical audiences	As requested via technical direction
4	General project support	As requested via technical direction

General Requirements of the Work Assignment and Schedule:

Due Dates: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.
Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents.
Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Technical Direction:
The WACOR or an authorized individual is permitted to provide technical direction. Technical direction must be within the statement of work of the contract and includes: (1) Direction to the contractor which assists the contractor in accomplishing the Statement of Work, (2) Comments on and approval of reports or other deliverables. Technical direction will be issued in writing or confirmed in writing within five (5) calendar days after verbal issuance. One copy of the technical direction memorandum will be forwarded to the Contracting Officer and the Contracting Officer Representative.

Contractor Identification:
The contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, the contractor personnel shall wear a badge which identifies the individual as a contractor employee. The contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

Confidentiality:
Some of the work assigned under these tasks will be to draft, edit and review sensitive program and organizational information. The contractor shall not discuss the contents of the conference or meeting discussions with anyone that did not participate in those discussions.

Notice Regarding Guidance Provided under this Work Assignment:

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the WACOR or the EPA Contracting Officer.

References

CDC Rec Water Outbreaks:

Alphabetical index of Water-Related Health Data:
http://www.cdc.gov/healthywater/statistics/surveillance/health_data.html

CDC Healthy Swimming Webpage: http://www.cdc.gov/healthywater/swimming/data/

Epidemiological studies:

"High Sensitivity of Children to Swimming-Associated Gastrointestinal Illness Results Using a Rapid Assay of Recreational Water Quality" Timothy J. Wade, Rebecca L. Calderon, Kristen P. Brenner, Elizabeth Sams, Michael Beach, Richard Haugland, Larry Wymer, and Alfred P. Dufour (Epidemiology 2008;19: 375–383)
http://journals.lww.com/epidem/Abstract/2008/05000/High_Sensitivity_of_Children_to.8.aspx

Marine Studies (P1, 2):
"Rapidly measured indicators of recreational water quality and swimming-associated illness at marine beaches: A prospective cohort study" Timothy J Wade , Elizabeth Sams, Kristen P Brenner , Rich Haugland , Eunice Chern , Michael Beach , Larry Wymer, Clifford C Rankin , David Love , Quanlin Li , Rachel Noble and Alfred P Dufour - Environmental Health 2010, 9:66doi:10.1186/1476-069X-9-66
Published: 31 October 2010
• Table S2: Adjusted Odds Ratios for illness risk among swimmers for a 1 log10 Increase in indicator density. Children age 10 and under.
http://www.ehjournal.net/imedia/3968942414721357/supp2.pdf

Epidemiological study in marine waters impacted by urban runoff in a temperate region (CD 5(a)):
"Report on 2009 National Epidemiologic and Environmental Assessment of Recreational Water Epidemiology Studies" Timothy J Wade , Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010.USEPA Report Number: EPA/600/R-10/168.
• Table 4.5, 4.6: Water exposures among children
• Tables 4.8-4.12: Incidence of illness among children
• Table 4.39, 4.42, 4.56, 4.57,
• Figure 5.16: Incidence of illness among children with regard to measures of water quality.
http://water.epa.gov/scitech/swguidance/waterquality/standards/criteria/health/recreation/index.cfm

Epidemiological study in a tropical region (CD 5(b)):
"Report on 2009 National Epidemiologic and Environmental Assessment of

Recreational Water Epidemiology Studies" Timothy J Wade , Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010.USEPA Report Number: EPA/600/R-10/168.

Wade, T. J., R. L. Calderon, et al. (2006). "Rapidly measured indicators of recreational water quality are predictive of swimming-associated gastrointestinal illness." Environ Health Perspect 114(1): 24-8.

Wade, T. J., N. Pai, et al. (2003). "Do U.S. Environmental Protection Agency Water Quality Guidelines for Recreational Waters Prevent Gastrointestinal Illness? A Systematic Review and Meta-analysis." Environmental Health Perspectives 111(8): 1102-1109.

Colford, J. M., Jr., T. J. Wade, et al. (2007). "Water Quality Indicators and the Risk of Illness at Beaches With Nonpoint Sources of Fecal Contamination." Epidemiology 18(1): 27-35.

Fleisher, J. M., F. Jones, et al. (1993). "Water and non-water-related risk factors for gastroenteritis among bathers exposed to sewage-contaminated marine waters." International Journal of Epidemiology 22(4): 698-708.

Fleisher, J. M., D. Kay, et al. (1996). "Marine waters contaminated with domestic sewage: nonenteric illnesses associated with bather exposure in the United Kingdom." Am J Public Health 86(9): 1228-34.

Kay, D., J. M. Fleisher, et al. (1994). "Predicting likelihood of gastroenteritis from sea bathing: results from randomised exposure." Lancet 344(8927): 905-9.

Wiedenmann, A., P. Kruger, et al. (2006). "A randomized controlled trial assessing infectious disease risks from bathing in fresh recreational waters in relation to the concentration of Escherichia coli,
intestinal enterococci, Clostridium perfringens, and somatic coliphages." Environ Health Perspect 114(2): 228-36.

Kay, D., N. Ashbolt, et al. (2006). "Reply to comments on "Derivation of numerical values for the World Health Organization guidelines for recreational waters"." Water Res 40(9): 1921-5.

Kay, D., J. Bartram, et al. (2004). "Derivation of numerical values for the World Health Organization guidelines for recreational waters." Water Res 38(5): 1296-304.

A description of EPI-BATHE can be found:
http://www.aber.ac.uk/iges/research/epibathe/favorite.htm

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-03

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-16-011	11/01/2016 To 06/30/2018 Base Option Period Number 1	Activities to support the deve

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1, 3.3, 3.6, 3.8

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 07/01/2017 To 06/30/2018

Comments:
Immediate Start Authorized

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2016 To 06/30/2018 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1101
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Contracting Official Name: Noelle Mills (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2171
	FAX Number:	

Performance Work Statement (PWS)
ICF Contract # EP-C-16-011
Work Assignment #1-03

Title: Activities to support the development of human health Ambient Water Quality Criteria (AWQC) for Cyanotoxins

Work Assignment Contracting Officer's Representative (WACOR):

John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Alternate WACOR:

Lesley D'Anglada (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-1125
E-mail: danglada.lesley@epa.gov

Period of Performance: July 1, 2017 through June 30, 2018

Contract PWS: 3.1, 3.3, 3.6, 3.8

****Note: No Confidential Business Information (CBI) data will be needed in the course of this work assignment.**

Background:

National Ambient Water Quality Criteria (AWQC) are established by the United States Environmental Protection Agency (EPA) pursuant to Section 304(a) of the Clean Water Act (CWA). The main goal of the CWA is to restore and maintain the chemical, physical, and biological integrity of the nation's waters. AWQC are recommendations developed and published by the EPA reflecting the latest scientific knowledge: (A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, including ground water; (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes; and (C) on the effects of pollutants on biological community diversity, productivity, and stability, including information on the factors affecting rates of eutrophication and rates of organic and inorganic sedimentation for varying types of receiving waters. CWA §304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of

meeting pollutant concentrations in ambient water. They are a non-regulatory, scientific assessment of effects on human health or aquatic life. The criteria recommendations developed from this effort are intended to be such scientific assessments.

The Environmental Protection Agency's (EPA) AWQC recommendations may be used by the states to establish water quality standards (WQS), and if adopted in state WQS and approved by EPA, will ultimately provide a basis for protecting the health of those recreating on or in the nation's waters. Additionally, the criteria also provide guidance to EPA when promulgating WQS for states under CWA §303(c), when such actions are necessary. When states adopt new or revised AWQC into WQS, they must be scientifically defensible and protective of the designated uses of the waterbodies. EPA's regulation 40 CFR §131.11(b)(1) provides that "In establishing criteria, states should (1) Establish numerical values based on (i) 304(a) Guidance; or (ii) 304(a) Guidance modified to reflect site-specific conditions; or (iii) Other scientifically defensible methods." For example, EPA published human health recreational water quality criteria (RWQC) recommendations in 2012 to describe the desired ambient water quality conditions to support the designated use of primary contact recreation (EPA, 2012). The 2012 RWQC are designed to protect swimmers from excess gastrointestinal illness caused by pathogens present in fecal contamination of waterbodies. This §304(a) criteria document recommends ambient water quality criteria values for cyanotoxins that would be protective of human health given a primary contact recreational exposure scenario. The cyanotoxins included in this effort have been demonstrated to occur in nutrient-enriched waters affected by a proliferation of cyanobacteria. Any recommended values produced from this effort do not replace or supersede the 2012 RWQC recommendations for recreational waters. Rather they are offered to supplement the 2012 RWQC to provide additional public health protection for additional, potentially hazardous conditions found in ambient recreational waters.

The water quality criteria developed from this effort are national ambient water quality criteria recommendations for the protection of human health. Unless expressly indicated otherwise, all references to "criteria", "water quality criteria", "ambient water quality criteria (AWQC) recommendations," or similar variants thereof, are references to national ambient water quality criteria recommendations for human health.

Quality Assurance:

The tasks (Tasks 2 -6) in this work assignment (WA) require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the approved ICF March 2017 final Programmatic QAPP (pQAPP) to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers secondary data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which

must be approved by the EPA before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the QA/quality control (QC) procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

Performance Work Statement (PWS): The contractor shall provide technical support in the development of AWQC for cyanotoxins. The scope of work in this assignment will fall under the following task areas:

Task Area 1 – Work Plan and Monthly Progress Reports

Task Area 1.1. *Work Plan*
The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task Area 1.2. *Monthly Progress Reports*
This task includes monthly progress and financial reports. The monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

As described in the Quality Assurance Section, the contractor must follow the ICF-submitted Nov 2016 draft pQAPP for the use of secondary data and, if applicable, application of peer reviewed existing model. This Nov 2016 pQAPP is currently under EPA review. The contractor shall comply with the EPA-approved version once it is in place. The monthly progress report shall indicate, in a separate QA section, whether significant project-specific QA issues have been identified and how they are being resolved.

Task 1.3: *Information Quality Guidelines*
The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (http://www.epa.gov/quality/informationguidelines/) and shall complete the Checklist for Influential Information, as needed, for each deliverable from this work assignment. The WACOR will provide this checklist to the contractor. The contractor shall have a teleconference with the WACOR before the initiation of Task 2 to discuss the Information Quality Guidelines and the contractor's role in completing the checklist. At the end of the work assignment, the contractor shall provide a memorandum describing how the planned product(s) developed for this work assignment meet with EPA's Checklist for Influential Information and documenting the quality assurance procedures that were used in developing the deliverables under this PWS.

Task Area 2 - Support for developing and editing cyanotoxin AWQC and AWQC-related documents

Task Area 2.1. *AWQC development*
The contractor shall assist the WACOR in developing AWQC documents or other related documents for cyanotoxins for the protection of human health. Risks from exposure to cyanobacteria can fall into two main categories: 1) inflammatory health endpoints associated with direct contact with the cells, and 2) intoxications via cyanotoxins produced by the bacteria. Cyanobacteria, also known as 'blue-green algae,' and are classified as microbial pollutants. The contractor shall refer to EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000) for a discussion of EPA's approved framework and parameter selection process. The document in development shall conform to Agency risk assessment guidance and be accessible to a non-technical audience for the purposes of informing decision-making. This task is iterative in nature and may require multiple revisions prior to publishing a final AWQC document. Analyses of monitoring data, such as characterizing correlations between toxin levels in surface waters and cyanobacterial cell counts or total phosphorus concentrations, may be necessary to support decisions in the development of the AWQC. White papers discussing specific topics and targeted literature searches may be needed (e.g., identification, collation and discussion of the amount of toxin produced by a cyanobacterial cell).

The contractor shall perform technical and editorial edits for all documents prepared and submit to the WACOR. Items, such as active voice and clear writing style, shall be addressed prior to submitting milestone deliverables (e.g., draft) to EPA. The contractor shall meet with the WACOR to discuss project planning and scoping prior to beginning work and then periodically thereafter, as needed.

Task Area 2.2. *Prepare briefing materials and other supporting documents to aid in AWQC development and communication efforts*

Briefing materials and other supporting documents will be needed during Final Agency Review, and during other parts of the Criteria development process. The contractor shall aid in the development of any materials or presentations for these purposes. It is anticipated that major decision points and/or document development milestones will require management briefings and supporting materials.

Task Area 3 – Response to Comments

Task Area 3.1. *Organizing and responding to comments.*
Draft AWQC will undergo several types of reviews before a final version is posted, including: internal management and technical reviews, expert peer-reviews, and public comment period. The contractor shall assist the WACOR with the response to comments for all reviews, revise the AWQC documents as requested, and provide an updated version to the WACOR. For the draft

document, the contractor can anticipate internal and external technical peer review comments and internal EPA office review comments. Additionally, the contractor should anticipate 3 rounds of management review at various levels.

Task Area 3.2. *Public Comment Analysis for the AWQC.*
The contractor shall continue to support EPA with addressing public comments on the published draft AWQC. Efforts under this task may also include comment analysis and summaries.

Task Area 4 – Gathering and preparing materials for the EPA docket

A "docket" is a collection of documents made available by an agency for public viewing often associated with an opportunity for public comment. EPA's dockets consist of materials used in developing a particular rulemaking or other action issued by the Agency. This task supported the publication of the draft criteria document in the Federal Register during the base year. EPA does not anticipate significant efforts under this task during option year 1. The task remains in this work assignment in case EPA would need to provide additional docket materials.

Task Area 4.1. *Prepare comprehensive list of materials needed in the docket*

The contractor shall help identify materials that need to be placed in the EPA docket. Docket materials may include, but are not limited to, publications, data, and meeting notes.

Task Area 4.2. *Gather and prepare materials needed in the docket*

Once the docket materials list has been reviewed by the WACOR, the contractor shall help gather and prepare all the materials that need to be placed in the EPA docket. Again, docket materials may include, but are not limited to, publications, data, and meeting notes.

Task Area 5 – Support ongoing Action Development Process Workgroup (ADP WG) efforts in the development of the RWQC

This task will require the contractor to assist in the ongoing efforts of the ADP WG. The contractor shall attend on-site ADP WG meetings, provide note-taking support, and submit meeting notes to the WACOR within 2 business days of each ADP WG meeting. Additionally, the contractor shall prepare meeting materials that may include, but are not limited to, presentations, briefing materials, hand-outs, and overviews. The number of workgroup meetings will depend on the number of decisions that require inter-office input, which is not known at this time. However, not more than 6 meetings are anticipated. The types of materials needed for each meeting will vary depending on the workgroup's need and topics discussed.

> Travel: Local travel is anticipated for this Task. No contractor travel outside of the Washington, D.C. metro area is required.

Task Area 6 - General Project Support

The contractor shall, based on technical direction given by the WACOR, provide support in conducting literature searches of the peer reviewed scientific literature—to address identified data gaps the searches would be specific and targeted in nature—and in preparing interim project updates and other materials for internal and external audiences. Literature searches will aid the development of the document conducted under Task 2. It is not known at this time how many searches would be needed, but for planning purposes, the Contractor may plan on four targeted searches. Additionally, specific data analyses may be required for briefings and/or communication materials. Such analyses would be based on technical direction given by the WACOR. These analyses are generally to support decision-making and usually have a defined scope to address specific risk management questions. Updates and other support materials may include, but are not limited to, short briefing documents, white papers and PowerPoint presentations. The WACOR may request the contractor to participate in and/or conduct briefings. A weekly update call with the WACOR will be required for this work assignment, as needed.

Some meetings may require contractor support and/or attendance for note-taking, presentations, and meeting preparation materials. Details on meeting dates and locations will be provided by the WACOR through technical direction, as further information becomes available. For planning purposes, the contractor can anticipate 3 meetings.

Travel: The contractor travel outside of the Washington, D.C. metro area may need to occur for this work assignment. Travel shall be in accordance with the requirements of the contract.

General Requirements of the Work Assignment and Schedule:

Due Dates: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.
Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.
Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.
Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Milestone/Deliverable Table.

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Per contract requirements

Information Quality Guidelines	1.2	Discuss with WACOR within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: Support for developing and editing cyanotoxin AWQC and AWQC-related documents		
AWQC development	2.1	After the workplan approval, throughout the period of performance. Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed.
Prepare briefing materials and other supporting documents to aid in AWQC development and communication efforts	2.2	As requested via technical direction
Task 3: Response to Comments		
Organizing and responding to comments	3.1	Will occur periodically throughout the period of performance during management and technical reviews of revisions to the draft AWQC and in preparing the final document. Exact dates TBD.
Public Comment Analysis for the AWQC	3.2	As requested via technical direction
Task 4: Gathering and preparing materials for the EPA docket		
Prepare comprehensive list of materials needed in the docket	4.1	As requested via technical direction
Gather and prepare materials needed in the docket	4.2	As requested via technical direction
Task 5: Support for ADP WG		The workgroup is likely to convene starting in late June and in July.
Task 6: General Project Support		As requested via technical direction

MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES AND RECEPTIONS:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA Contract Level Contracting Officer's Representative (CL-COR) as needed and provided to the Contracting

Officer (CO). Work under conference related activities that involves $20,000 or more in net expenses shall not occur until this approval is obtained and provided by the CO.

TECHNICAL DIRECTION:
The WACOR or the Alternate WACOR is permitted to provide technical direction. Technical direction must be within the statement of work of the contract and includes: (1) Direction to the contractor which assists the contractor in accomplishing the Statement of Work, (2) Comments on and approval of reports or other deliverables. Technical direction will be issued in writing or confirmed in writing within five (5) calendar days after verbal issuance. One copy of the technical direction memorandum will be forwarded to the CO and the CL-COR.

CONTRACTOR IDENTIFICATION:
The contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, contractor personnel shall wear a badge which identifies the individual as a contractor employee. The contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

SPECIAL CONDITIONS:
A. The contractor shall provide all materials written under these tasks to the WACOR, as per work assignment, in electronic form and 5 hard copies of the final products. Electronic versions shall be in Microsoft Word and/or PDF.

B. The contractor shall provide signed copies of all consultant agreements for the experts required in support of this work assignment to the EPA Contracting Officer.

CONFIDENTIALITY:
Some of the work assigned under these tasks will be to draft, edit and review sensitive program and organizational information. The contractor shall not discuss the contents of the conference or meeting discussions with anyone that did not participate in those discussions.

NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT:

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the WACOR or the EPA Contracting Officer.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-03

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-16-011	11/01/2016 To 06/30/2018 Base Option Period Number 1	Activites to Support the Devel

Contractor	Specify Section and paragraph of Contract SOW
ICF Incorporated, L.L.C.	3.1,3.3,3.6,3.8

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 07/01/2017 To 06/30/2018

Comments:
The purpose of this amendment is to provide additional LOE under Task areas 2 through 6 to support HECD's review of the scientific information related to cyanobacteria and cyanotoxins and to develop recreational criteria for the cyanotoxins, microcystins and cylindrospermopsin. See attached PWS.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2016 To 06/30/2018		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:	Cost/Fee	LOE:

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1101 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Noelle Mills (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2171 FAX Number:

Performance Work Statement (PWS)
ICF Contract # EP-C-16-011
Work Assignment #1-03
Amendment 1

Title: Activities to support the development of human health Ambient Water Quality Criteria (AWQC) for Cyanotoxins

Work Assignment Contracting Officer's Representative (WACOR):

John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Alternate WACOR:

Lesley D'Anglada (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-1125
E-mail: danglada.lesley@epa.gov

Period of Performance: Date of Issuance through June 30, 2018

Contract PWS: 3.1, 3.3, 3.6, 3.8

****Note: No Confidential Business Information (CBI) data will be needed in the course of this work assignment.**

Purpose of Amendment: The purpose of this amendment is to provide additional LOE under Task areas 2 through 6 to support HECD's review of the scientific information related to cyanobacteria and cyanotoxins and to develop recreational criteria for the cyanotoxins, microcystins and cylindrospermopsin. Deliverables under these tasks and discussed in the approved workplan have required a more detailed approach, additional revisions, and more effort to draft and to respond to internal review and editing than anticipated. For example, additional analyses and literature review have been needed to respond to multiple rounds of internal and external comments made by EPA and stakeholders. The additional LOE supplied by this amendment will support the preparation of useful deliverables of sufficient quality for EPA and ensure tight project timelines. Unless specifically mentioned otherwise below, the language contained in the original work assignment still applies (e.g., Information Quality Guidelines, QA section, etc.). The contractor shall submit a revised cost estimate within 5 days for this amendment.

Milestone/Deliverable Table.

Task	Task #	Milestones and Due Dates
Task 2: Support for developing and editing cyanotoxin AWQC and AWQC-related documents		
AWQC development	2.1	After the workplan approval, throughout the period of performance. Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed.
Prepare briefing materials and other supporting documents to aid in AWQC development and communication efforts	2.2	To Be Determined (TBD)
Task 3: Response to Comments		
Organizing and responding to comments	3.1	Will occur periodically throughout the period of performance during management and technical reviews of revisions to the draft AWQC and in preparing the final document. Exact dates TBD.
Public Comment Analysis for the AWQC	3.2	TBD
Task 4: Gathering and preparing materials for the EPA docket		
Prepare comprehensive list of materials needed in the docket	4.1	TBD
Gather and prepare materials needed in the docket	4.2	TBD
Task 5: Support for ADP WG		The workgroup is likely to convene starting in late June and in July.
Task 6: General Project Support		TBD

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-03

☐ Other ☒ Amendment Number: 000002

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-16-011	11/01/2016 To 06/30/2018 Base Option Period Number 1	Cyanotoxin AWQC Development

Contractor	Specify Section and paragraph of Contract SOW
ICF Incorporated, L.L.C.	3.1, 3.3, 3.6, 3.8

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 07/01/2017 To 06/30/2018

Comments:
The purpose of this amendment is to add additional LOE for the continued support of development of recreational criteria for the cyanotoxins, microcystins and cylindrospermopsin. See attached PWS for details.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2016 To 06/30/2018		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1101 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)		Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

Performance Work Statement (PWS)
ICF Contract # EP-C-16-011
Work Assignment #1-03 Amd 2

Title: Activities to support the development of human health Ambient Water Quality Criteria (AWQC) for Cyanotoxins

Work Assignment Contracting Officer's Representative (WACOR):

John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Alternate WACOR:

Lesley D'Anglada (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-1125
E-mail: danglada.lesley@epa.gov

Period of Performance: Date of Issuance through June 30, 2018

Contract PWS: 3.1, 3.3, 3.6, 3.8

****Note: No Confidential Business Information (CBI) data will be needed in the course of this work assignment.**

PURPOSE OF AMENDMENT: The purpose of this amendment is to add additional LOE for the continued support of development of recreational criteria for the cyanotoxins, microcystins and cylindrospermopsin. Deliverables under these tasks and discussed in the approved workplan, specifically Tasks 2 and 3, have required a more detailed approach, additional revisions, and more effort to draft and to respond to internal review and editing than anticipated. Remaining actions under these tasks include: additional revision to the 'response-to-public-comments' document, additional revisions of the criteria by management and the ADP workgroup members, and support for preparation of materials for the next ADP workgroup meeting (Task 5, low level). The additional LOE supplied by this amendment will support the preparation of useful deliverables of sufficient quality for EPA and ensure tight project timelines during preparation of the final deliverable to meet EPA's goal of publishing the criteria by Spring, 2018.

There are no new tasks and all existing tasks are the same. The language contained in the original work assignment still applies (e.g., Information Quality Guidelines, QA section, etc.). The Contractor shall submit a cost estimate within five days of receiving this amendment.

Milestone/Deliverable Table.

Task	Task #	Milestones and Due Dates
Task 2: Support for developing and editing cyanotoxin AWQC and AWQC-related documents		
AWQC development	2.1	After the workplan approval, throughout the period of performance. Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed.
Prepare briefing materials and other supporting documents to aid in AWQC development and communication efforts	2.2	To Be Determined (TBD)
Task 3: Response to Comments		
Organizing and responding to comments	3.1	Will occur periodically throughout the period of performance during management and technical reviews of revisions to the draft AWQC and in preparing the final document. Exact dates TBD.
Public Comment Analysis for the AWQC	3.2	Initial analysis complete. Additional analyses may be required based on management feedback.
Task 4: Gathering and preparing materials for the EPA docket		
Prepare comprehensive list of materials needed in the docket	4.1	TBD
Gather and prepare materials needed in the docket	4.2	TBD
Task 5: Support for ADP WG		The workgroup is likely to convene again in February and March. Additional comments and revisions expected.
Task 6: General Project Support		TBD

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-04

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-16-011	11/01/2016 To 06/30/2018 Base Option Period Number 1	Activities for RWQC Coliphage

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1, 3.2, 3.3, 3.4, 3.6, 3.7, 3.8

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 07/01/2017 To 06/30/2018

Comments: Immediate Start Authorized

[ ] Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): [ ]

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2016 To 06/30/2018		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Sharon Nappier (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-0740
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Contracting Official Name: Noelle Mills (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2171
	FAX Number:	

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-16-011
WORK ASSIGNMENT #1-04

Title: Activities to support the development of Recreational Water Quality Criteria for Coliphage

Work Assignment Contracting Officer Representative (WACOR):
Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Alternate WACOR:
Lesley D'Anglada (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1125
E-mail: danglada.lesley@epa.gov

Period of Performance: Date of issuance through June 30, 2018

Contractor SOW: 3.1, 3.2, 3.3, 3.4, 3.6, 3.7, 3.8

****Note: No CBI data will be needed in the course of this work assignment.**

Background:
Human health recreational water quality criteria (RWQC) are numeric values limiting the amount of chemical or microbial agents present in our nation's waters. Human health criteria are developed under Section 304(a) of the Clean Water Act (CWA) of 1972 and are designed to protect human health. Water quality criteria are developed by assessing the relationship between pollutants and their effect on human health and the environment. These criteria are used by states and Indian tribes to establish water quality standards and ultimately provide a basis for controlling discharges or releases of pollutants.

The Environmental Protection Agency (EPA) has published RWQC for bacteria. Historically, EPA has based the bacteria criteria on fecal indicator bacteria (FIB). These organisms do not generally cause human illness themselves (that is, they are not human pathogens); rather, they are indicators of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

The EPA is now interested in creating RQWC to protect against viral illnesses using coliphage, a viral indicator. EPA believes that these virus criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection.

Quality Assurance:
The tasks 2-4 in this work assignment require the use of existing data and application of existing, peer reviewed models. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the Agency approved ICF March 2017 Programmatic Quality Assurance Project Plan (pQAPP) for Collection, Use, and Analysis (including Model Application) of Existing Data in order to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers existing data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The contractor shall comply with the March 2007 EPA approved pQAPP. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a work assignment-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the Quality Assurance and Quality Control (QA/QC) procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

Performance Work Statement (PWS): The scope of work in this assignment will fall under the following task areas:

Task 1: Work plan and monthly progress reports

Task 1.1 Work Plan
The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential

issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task 1.2 Monthly Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.3 Information Quality Guidelines

Task 1.3: *Information Quality Guidelines.* The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (IQG) (www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information. The contractor shall complete the OW IQG Checklist as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the OW IQG checklist. The WACOR will provide the checklist to the contractor. At the end of the work assignment, the contractor shall provide a memorandum describing how the planned product(s) developed meet the requirements of the OW's IQG checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this work assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report.

TASK 2 – Coliphage Experts Workshop Proceedings

In March 2016, EPA held a Coliphage Experts Workshop to obtain input on science questions from experts in the fields of environmental microbiology, microbial risk assessment, and environmental epidemiology. This workshop represents one part of a series of EPA-led efforts to inform criteria development with the latest scientific thinking, and ultimately, provide recommendations to State and Tribal partners. The goal of the workshop was not to reach consensus, rather, it was designed to be a critical thinking and information gathering exercise.

2016 Coliphage Expert Workshop Proceedings: A Workshop Proceedings document has been drafted and independently peer-reviewed. The contractor shall make edits to the Proceedings based on multiple reviews, including but not limited to, internal management reviews, Expert participant reviews, and an independent peer-review. The

contractor shall incorporate changes and comments into the Workshop Proceedings and return edits to WACOR at a date specified by the WACOR. The contractor shall ensure the Final Coliphage Experts Workshop Proceedings version published by the EPA is 508 compliant.

TASK 3 – Viral distributions

Task Area 3.1 *Literature reviews.* This task is a continuation of earlier efforts to characterize the densities of viruses in raw sewage (influent), in effluent, and in ambient waters. Through Technical Direction by the WACOR, the contractor shall collect and evaluate viral density data in the aforementioned matrices from the peer-review literature, grey literature, and from utilities, when available. Viruses reviews may include, but are not limited to, male-specific and somatic coliphage, norovirus, adenovirus, enterovirus, and reovirus.

Task Area 3.2 *Literature review publications.* A series of publications may result from the literature reviews in Task Area 3.1. The contractor shall prepare the data and information for submission, perform edits after the work has received internal EPA reviews, and submit the manuscript to the journal. The contractor will also be responsible for responding to reviewer comments and completing final edits.

TASK 4 – Recreational Water Quality Criteria Coliphages

Task Area 4.1 *Scope of the Criteria Documents.* This task will require the contractor to assist scoping the RWQC for coliphage for potentially multiple designated uses, such as primary contact recreation and drinking water. Under this task area, the contractor shall assist in drafting an outline of the coliphage-based criterion and identifying the needs of the criterion documents.

Task Area 4.2 *Derivation of the Criteria Values.* This task is a continuation of earlier efforts to use risk assessment and other statistical methods to develop RWQC values for coliphage. Risk assessments will rely heavily on data collected in Task 3 through Technical Direction by the WACOR, the contractor shall develop RWQC values to be used in future criteria for coliphage.

Task Area 4.3 *Develop Criterion Document Drafts.* Under this task area, the contractor shall provide draft documents of the RWQC for coliphage. This task will be an ongoing effort for the period of performance of this work assignment and a series of Drafts are expected for internal purposes, for peer-review, and for public comment.

Task Area 4.4 *Prepare and submit Final RWQC Criteria for Coliphage.* The contractor shall prepare and submit a Final RWQC document. This document shall be 508 Compliant and formatted as directed by the WACOR.

Task Area 4.5 *Prepare briefing materials and other supporting documents pertaining to the Coliphage-based RWQC documents.* Briefing materials and other supporting documents will be needed during the Criteria development process. The contractor shall aid the in the development of any materials or presentations for these purposes.

TASK 5- General Project Support

The contractor shall, based on technical direction given by the WACOR, provide support in preparing interim project update and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractors may also be requested to participate in and/or conduct briefings. A weekly update call with the WACOR will be required for this work assignment, as needed.

Some meetings may require contractor support and/or attendance for note-taking, presentations, and meeting preparation materials. Details on travel dates and locations will be provided by the WACOR through technical direction, as further information becomes available.

Travel: Travel may be needed as deemed necessary by the WACOR. This PWS will provide travel funds for up to eight trips for contractors and/or subcontractors to travel to Washington DC and to conferences, which may include, but are not limited to, the 2017 UNC Water Microbiology Conference (May 15-19) in Chapel Hill, NC.

Schedule and Deliverables:

Task No.	Deliverable	Schedule
1.1	**Workplan**	Per contract requirements
2	**DRAFT Coliphage Experts Workshop Proceedings – edits from Peer-review**	Two weeks after receipt of draft from WACOR
2	**DRAFT Coliphage Experts Workshop Proceedings – edits from final EPA review**	One weeks after receipt of draft from WACOR
2	**Coliphage Experts Workshop Proceedings – 508 compliant**	As requested via technical direction
3.1	**Literature Reviews**	As requested via technical direction
3.2	**Literature Review publications**	As requested via technical direction
4.1	**Scope and outline of RWQC**	As requested via technical direction
4.2	**Criteria derivation efforts**	As requested via technical direction
4.3	**RWQC document – DRAFTS (internal, peer-review, public comment)**	As requested via technical direction
4.4	**RWQC document – FINAL (508)**	As requested via technical direction
4.5	**Briefing materials, supporting documents, presentations**	As requested via technical direction

5	**General Project Support**	As requested via technical direction

Knowledge and Skills Required:

The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology and/or environmental engineering. The contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

General Requirements of the Work Assignment and Schedule:

Due Dates: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-04

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-16-011	11/01/2016 To 06/30/2018 Base Option Period Number 1	Coliphage

Contractor	Specify Section and paragraph of Contract SOW
ICF Incorporated, L.L.C.	3.1, 3.2, 3.3, 3.4, 3.6, 3.7, 3.8

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 07/01/2017 To 06/30/2018

Comments:
The purpose of this work assignment amendment is to provide additional LOE to support efforts related to efforts related to the development of Recreational Water Quality Criteria for Coliphage.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2016 To 06/30/2018		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee	LOE:
Cumulative Approved:	Cost/Fee	LOE:

Work Assignment Manager Name: Sharon Nappier (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-0740 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Noelle Mills (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2171 FAX Number:

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-16-011
WORK ASSIGNMENT #1-04 Amendment 1

Title: Activities to support the development of Recreational Water Quality Criteria for Coliphage

Work Assignment Contracting Officer Representative (WACOR):
Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Alternate WACOR:
Lesley D'Anglada (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1125
E-mail: danglada.lesley@epa.gov

Period of Performance: Date of issuance through June 30, 2018

Contractor SOW: 3.1, 3.2, 3.3, 3.4, 3.6, 3.7, 3.8

Purpose of the Amendment: The purpose of this work assignment amendment is to provide additional LOE to support efforts related to efforts related to the development of Recreational Water Quality Criteria for Coliphage. *Tasks 3, 4 and 5 remain the same, no change. Task 2 has been completed.* Travel for up to three trips is added in Amendment 1. Travel details will be provided by the COR. The contractor shall submit a revised cost estimate within 5 days of this amendment.

Schedule and Deliverables:

Task No.	Deliverable	Schedule
1	**Workplan – revised cost estimate**	Within 5 calendar days
2	**DRAFT Coliphage Experts Workshop Proceedings – edits from Peer-review**	COMPLETED
2	**DRAFT Coliphage Experts Workshop Proceedings – edits from final EPA review**	COMPLETED
2	**Coliphage Experts Workshop Proceedings – 508 compliant**	COMPLETED
3.1	**Literature Reviews**	TBD
3.2	**Literature Review publications**	TBD
4.1	**Scope and outline of RWQC**	TBD
4.2	**Criteria derivation efforts**	TBD
4.3	**RWQC document – DRAFTS (internal, peer-review, public comment)**	TBD
4.4	**RWQC document – FINAL (508)**	TBD
4.5	**Briefing materials, supporting documents, presentations**	TBD
5	**General Project Support**	TBD

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-05

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-16-011	11/01/2016 To 06/30/2018 Base Option Period Number 1	Activ to support Water Reuse

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1, 3.3, 3.4, 3.6, 3.7, 3.8

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 07/01/2017 To 06/30/2018

Comments: Immediate Start Authorized

[ ] Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): [ ]

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2016 To 06/30/2018		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:		Cost/Fee	LOE:
Cumulative Approved:		Cost/Fee	LOE:

Work Assignment Manager Name: Sharon Nappier (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-0740
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Contracting Official Name: Noelle Mills (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2171
	FAX Number:	

PERFORMANCE WORK STATEMENT (PWS)
ICF CONTRACT EP-C-16-011
WORK ASSIGNMENT #1-05

Title: Activities to support the Environmental Protection Agency's (EPA) water reuse efforts

Work Assignment Contracting Officer's Representative (WACOR):
Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Alternate WACOR:
Lesley D'Anglada (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1125
E-mail: danglada.lesley@epa.gov

Period of Performance: July 1, 2017 through June 30, 2018

Contractor PWS: 3.1, 3.3, 3.4, 3.6, 3.7, 3.8

****Note: No Confidential Business Information data will be needed in the course of this work assignment.**

Background:

Currently there are no Federal regulations for water reuse. Rather, water reclamation and reuse standards in the United States are the responsibility of state and local agencies. In 1980, the Environmental Protection Agency (EPA) developed the first Guidelines for Water Reuse as a technical research report for Office of Research and Development (ORD). There have been several updates to this Guidance, with the most recent being the 2012 Guidelines for Water Reuse.

Indirect Potable Reuse (IPR) occurs when a utility discharges reclaimed water (treated effluent) to an environmental buffer such as a surface water or groundwater supply and this reclaimed water augments the drinking water supply.

Direct Potable Reuse (DPR), for the purposes of this PWS, means the use of water from a regulated wastewater treatment or recycling facility that is introduced into the drinking water treatment facility without the use of an environmental buffer. For the purposes of this PWS, DPR does not include the introduction of water from a recycling facility directly into a drinking water distribution system.

Non-potable Reuse (NPR) is the use of reclaimed water for recreational, agricultural or other uses where direct human ingestion of the water does not occur. Recreational non-potable reuse can include snowmaking. Agricultural non-potable water reuse includes irrigation of food crops intended for human or animal consumption.

Water availability and drought are driving a number of states to examine water reuse as an alternative source of water for potable and non-potable applications. In many states, drinking water utilities are at various stages in considering implementing water reuse. An increasing number of states have been contacting EPA asking for guidance when they are approached by utilities that are contemplating or commencing the process of implementing DPR. As of the writing of this PWS, a number of states have adopted regulations, guidelines or design standards to cover their water reuse activities. Several states address direct or indirect potable reuse including California, Arizona, New Mexico, Texas, Colorado, Florida, Georgia, Virginia, Wyoming and Washington.

However, there are still scientific gaps relating to potable and non-potable water reuse safety, especially because states are moving forward with different standards and treatment trains and because there is a gap in the knowledgebase for assessing potential human health risks from various routes of exposure to recycled water. For example, many of these safety concerns relate to the risks associated with exposure to chemicals (including mixtures) and microbes in the finished potable water. This work assignment will address human health risks via Quantitative Microbial Risk Assessment (QMRA) from pathogen exposures to various potable and non-potable reuse applications and subsequent exposure routes, including treatment trains currently in use or currently under consideration.

QUALITY ASSURANCE

The tasks 2 and 3 in this work assignment require the use of existing data and application of existing, peer reviewed models. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the Agency approved ICF March 2017 Programmatic Quality Assurance Project Plan (pQAPP) for Collection, Use, and Analysis (including Model Application) of Existing Data in order to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers existing data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The contractor shall comply with the March 2007 EPA approved pQAPP. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a work assignment-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the Quality Assurance and Quality Control (QA/QC) procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

Performance Work Statement: The scope of work in this assignment will fall under the following task areas:

Task 1: Work plan and monthly progress reports

Task 1.1 Work Plan
The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2 Information Quality Guidelines
The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's

Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this work assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

TASK 2 – Quantitative Microbial Risk Assessment of Water Reuse Scenarios

The contractor shall develop QMRAs to support Health and Ecological Criteria Division (HECD) efforts to estimate human health risks from various exposure routes and water reuse scenarios. The scenarios may include defacto, indirect, or direct reuse applications. The contractor shall develop appropriate planning and scoping activities prior to conducting risk analyses. Planning and scoping activities will include the delineation of the important risk management questions and potential science gaps that the assessment could address. Additionally, these activities shall include the identification of the exposure routes of interest, relevant pathogens and pathogen indicators, etc. The contractor shall also develop a problem formulation, including a data inventory, for any reuse scenario that is modeled. The contractor shall develop a risk characterization for each QMRA conducted under this task that discusses the interpretation of the risk modeling and analyses. This interpretation shall be a synthesis exercise and include sensitivity and uncertainty analysis and interpretation. The contractor shall frame the risk characterization to reflect the problem formulation such that it is useful for informing decision-making at the EPA. The contractor shall coordinate these activities with the WACOR.

Task 2.1 *Distributions of Pathogens and pathogen indicators*

As part of ongoing work in WA B-04, the contractor shall update, as specified by the WACOR, distributions of pathogenic protozoa, bacteria, and viruses in raw sewage, ambient water, and in effluent that has undergone various stages of treatment or retention time. Viruses can include coliphage, norovirus, adenovirus, rotavirus, etc. Protozoans can include, but are not limited to, *Giardia spp.* and *Cryptosporidium spp*. Bacteria can include, but are not limited to, *Legionella* spp., *E. coli* O157:H7, *Campylobacter* spp., etc. Additionally, the contractor may also be required to develop distributions of pathogen indicators as needed and specified by the WACOR.

Task 2.2 *QMRAs to evaluate water reuse*

Using the pathogen distribution information developed under task 2.1 and/or information provided by the WACOR, the contractor shall conduct QMRAs for estimating human health risks from exposure to waters that have undergone multiple treatment trains and are intended for use under various water reuse scenarios. Multiple treatment train and disinfectant configurations may be explored.

Additionally, as requested by the WACOR, the contractor shall conduct a QMRA for other exposure and water reuse scenarios as needed to help inform decision making in EPA's Office of Water. Risk assessments may include, but are not limited to, defacto reuse, indirect water reuse, and decentralized water reuse configurations. Several circumstances may be evaluated, such as treatment failures and outbreak scenarios.

Task 2.3 *Evaluation of log-reduction credit recommendations*

While there are no national regulatory recommendations in the United States for the potable reuse of water, California has developed microbial log-reduction regulations for groundwater replenishment IPR projects. California's groundwater IPR regulations include a 12-log removal of enteric viruses, 10-log removal of *Cryptosporidium* spp., and Giardia (also known as the "12-10-10 Rule"), using at least three treatment processes (from wastewater treatment through advanced treatment) with no single process given a removal credit greater than 6-log. California may also use the 12-10-10 Rule for IPR surface water augmentation regulations and is considering statewide DPR regulations. The aforementioned "12-10-10 Rule" is based on a risk goal of 1 infection per 10,000 people per year and the maximum reported densities of culturable enteric viruses, *Giardia lamblia*, and *Cryptosporidium* spp. found in raw sewage. Recent literature, however, suggests that different reference viruses and new dose-response models also should be considered in the aforementioned log-reduction goal calculations.

For DPR projects in Texas, the minimum log removal and/or inactivation targets are 8-log for enteric virus, 5.5-log for *Cryptosporidium* spp., and 6-log for Giardia for the advanced treatment system (not including the wastewater treatment plant). These targets are considered a starting point for the approval process and may be revised on a case-by-case basis taking into consideration data collected from the wastewater effluent in question. Texas also uses a health risk goal of 1 infection per 10,000 people per year as a benchmark.

Using information collected in Task 2.1 and from previous Work Assignments, as specified by the WACOR, the contractor shall evaluate log-reduction credits currently recommended by various states for reuse applications. Additionally, the contractor shall evaluate log-reduction credits currently allocated by states, such as CA and TX, to various unit treatment processes (ex: ultraviolet disinfection, reverse osmosis, microfiltration, etc).

Task 2.4 *EPA Reports, Technical Guides, and Publications*

The contractor shall submit deliverables from 2.1-2.3 work as both an EPA report for internal review and as a peer-review publication manuscript. EPA anticipates there will be several internal reviews of both the EPA report and manuscript prior to publication. Regarding manuscripts, the contractor shall prepare the data and information for

submission, preform edits after the work has received internal EPA reviews, and submit the manuscript to the journal. The contractor shall also be responsible for responding to reviewer comments and completing final edits. At the WACOR's request, the contractor shall make the final EPA reports 508 compliant.

EPA may also choose to publish a series of Technical Guides based on the results conducted in Task 2.1-2.3 and on additional published water reuse literature. The contractor shall assist in outlining, drafting, editing, and finalizing Technical Guides. At the WACOR's request, the contractor shall make the final EPA document 508 compliant.

> *Travel:* Local travel is anticipated for this Task. No contractor travel outside of the Washington, D.C. metro area is required.

Task Area 3 - General Project Support

The contractor shall, based on technical direction given by the WACOR, provide support in conducting literature searches of the peer reviewed scientific literature and in preparing interim project updates and other materials for internal and external audiences. Literature searches will aid the development of the QMRAs conducted under Task 2. Updates and other support materials may include, but are not limited to, short briefing documents, white papers and PowerPoint presentations. The contractors may also be requested to participate in and/or conduct briefings. A weekly update call with the WACOR will be required for this work assignment, as needed.

Some meetings may require contractor support and/or attendance for note-taking, presentations, and/or meeting preparation materials. Details on travel dates and locations, for up to seven trips, will be provided by the WACOR through technical direction, as further information becomes available.

> Travel: Travel may be needed as deemed necessary by the WACOR.

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology. The contractor shall be familiar with viral, protozoan, and bacterial indicators and pathogens, microbiological analytical methods (including molecular techniques), biostatistics, quantitative microbial risk assessment, environmental engineering, and direct and indirect potable water reuse. The contractor shall be familiar with the interpretation of indicator and pathogen monitoring results and how those results are related to risk estimates and public health protection.

General Requirements of the Work Assignment and Schedule:

Due Dates: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.
Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.
Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.
Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Per contract requirements
Information Quality Guidelines	1.2	Discuss with WACOR within 20 calendar days after receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: Quantitative Microbial Risk Assessment		Initial planning meeting to be held within 20 calendar days after receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed. For each QMRA that is conducted, the contractor shall meet with the WACOR to discuss planning and scoping and develop the problem formulation.
Updated distributions of pathogens and pathogen indicators	2.1	As requested via technical direction
QMRAs	2.2	As requested via technical direction
Evaluation of log-reduction credits	2.3	As requested via technical direction

PA Reports, Technical Guides, and Peer-reviewed Publications	2.4	Unless specified by the WACOR, the schedule for report and manuscript deliverables is as follows (please note that not all draft deliverable milestones will apply to all deliverables): Reports/Technical Guides: Draft for Mgmt review – 2 weeks after receiving WACOR comments; Draft for peer review – 1 week after receiving EPA Mgmt. comments; Final for Mgmt review – 2 weeks after receiving peer review comments; Final for publication – 2 weeks after receiving EPA Mgmt comments. Manuscripts: Draft for Mgmt review – 2 weeks after receiving WACOR comments; Final – 1 week after receiving EPA Mgmt comments and approval.
Task 3: General Project Support		TBD

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-05

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-16-011	11/01/2016 To 06/30/2018 Base Option Period Number 1	Activities support water reuse

Contractor	Specify Section and paragraph of Contract SOW
ICF Incorporated, L.L.C.	3.1, 3.3, 3.4, 3.6, 3.7, 3.8

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 07/01/2017 To 06/30/2018

Comments:
The purpose of this work assignment amendment is to provide additional LOE to support efforts related to the development of water reuse risk assessments and associated reports, technical guides, and manuscripts.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (Max 2): ☐

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2016 To 06/30/2018		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:	Cost/Fee	LOE:

Work Assignment Manager Name: Sharon Nappier (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-0740
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Contracting Official Name: Noelle Mills (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2171
	FAX Number:	

PERFORMANCE WORK STATEMENT (PWS)
ICF CONTRACT EP-C-16-011
WORK ASSIGNMENT #1-05, Amendment 1

Title: Activities to support the Environmental Protection Agency's (EPA) water reuse efforts

Work Assignment Contracting Officer's Representative (WACOR):
Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Alternate WACOR:
Lesley D'Anglada (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1125
E-mail: danglada.lesley@epa.gov

Period of Performance: Date of Issuance through June 30, 2018

Contractor PWS: 3.1, 3.3, 3.4, 3.6, 3.7, 3.8

****Note: No Confidential Business Information data will be needed in the course of this work assignment.**

Purpose of the Amendment: The purpose of this work assignment amendment is to provide additional LOE to support efforts related to the development of water reuse risk assessments and associated reports, technical guides, and manuscripts. *Tasks 1, 2, and 3 remain the same, no change. Travel for up to four trips were added in Amendment 1.* Travel details will be provided by the COR. The contractor shall submit a revised cost estimate within 5 days of this amendment.

Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Within 20 calendar days after receipt of work assignment
Information Quality Guidelines	1.2	Discuss with WACOR within 20 calendar days after receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: Quantitative Microbial Risk Assessment		Initial planning meeting to be held within 20 calendar days after receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed. For each QMRA that is conducted, the contractor shall meet with the WACOR to discuss planning and scoping and develop the problem formulation.
Updated distributions of pathogens and pathogen indicators	2.1	To Be Determined (TBD)
QMRAs	2.2	TBD
Evaluation of log-reduction credits	2.3	TBD
PA Reports, Technical Guides, and Peer-reviewed Publications	2.4	Unless specified by the WACOR, the schedule for report and manuscript deliverables is as follows (please note that not all draft deliverable milestones will apply to all deliverables): Reports/Technical Guides: Draft for Mgmt review – 2 weeks after receiving WACOR comments; Draft for peer review – 1 week after receiving EPA Mgmt. comments; Final for Mgmt review – 2 weeks after receiving peer review comments; Final for publication – 2 weeks after receiving EPA Mgmt comments. Manuscripts: Draft for Mgmt review – 2 weeks after receiving WACOR comments; Final – 1 week after receiving EPA Mgmt comments and approval.
Task 3: General Project Support		TBD